

REMARKS

Claims 1-36 will be pending upon entry of the presently made amendments. Claims 3-21, 24, 25 and 36 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1 and 2 have been amended without prejudice to recite methods of treatment.

Claim 31 has been amended to clarify that the pain can be “associated with” one of the recited conditions. Support for this amendment is found in the specification as filed at least at page 20, lines 17-19 and page 49, lines 10-13.

Applicants have amended the Title to more accurately reflect the amended claims.

No new matter has been added.

Applicants reserve their right to prosecute the subject matter of any canceled claim, any amended claim, any withdrawn claim or any unclaimed subject matter in one or more related applications.

I. The Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 31 is rejected under 35 U.S.C. § 112, second paragraph. In particular, it appears that the Examiner has rejected claim 31 for reciting that the pain can be “lost hair, dry hand, color change to the skin, etc.”.

Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claim 31 to recite that the pain can be “associated with” recited conditions.

Accordingly, Applicants submit that the rejection of claim 31 under 35 U.S.C. § 112, second paragraph, has been overcome and should be withdrawn.

II. The Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1, 2, 22, 23 and 26-35 are rejected under 35 U.S.C. § 112, first paragraph. In particular, while acknowledging that the specification is enabling for the treatment of pain, the Examiner has stated that it does not reasonably provide enablement for the prevention of pain.

Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claims 1 and 2 to recite methods of treatment. Claims 22, 23 and 26-35 depend directly or indirectly from claims 1 or 2.

Accordingly, Applicants submit that the rejection of claims 1, 2, 22, 23 and 26-35 under 35 U.S.C. § 112, first paragraph, has been overcome and should be withdrawn.

III. The Rejection Under 35 U.S.C. § 102(e) over U.S. Patent No. 6,897,231 B2

Claims 1 and 28-35 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,897,231 B2 to Bhagwat *et al.* (the “’231 patent”). In particular, the Examiner has stated that the ’231 patent teaches the prevention of pain associated with the diseases disclosed therein by preventing or treating the diseases that cause pain.

Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claims 1 and 2 to recite methods for treatment. Claims 28-35 depend directly or indirectly from claim 1.

Applicants respectfully submit that the claimed methods for treating pain are not anticipated by the ’231 patent because pain is separate and distinct from disease, wherein the treatment of a particular disease does not necessarily treat pain. As discussed in Applicant’s Response to Office Action Under 37 C.F.R. § 1.111 as filed on July 30, 2007 in connection with the present application, the current paradigm in clinical pain management recognizes that it is essential to differentiate etiological factors or disease/causative factors from pain mechanisms themselves. *See* second paragraph at page S142 of Woolf and Decosterd, 1999, “Implications of recent advances in the understanding of pain pathophysiology for the assessment of pain in patients,” *Pain Supplement 6*:S141-S147 (previously submitted as reference C01). In other words, treatment of an underlying condition is unlikely to treat pain associated with the condition and, in fact, disease-based classification for treating pain is discouraged. *See* second paragraph at page S142 of Woolf and Decosterd. Indeed, it is now recognized that the pain itself is the disease. *See* second full paragraph at page S145 of Woolf and Decosterd; and last sentence of “Summary” at page 31 of R.A. Sternbach, 1981, “Chronic Pain as a Disease Entity,” *Triangle 20*(1/2):27-30 (previously submitted as reference C02). Accordingly, Applicants respectfully submit that the pending method for treatment claims are indeed directed to novel methods of use and do not read upon the subject matter of the ’231 patent.

Applicants again note that phantom limb pain is an especially useful example for illustrating the disconnect between an underlying condition and pain itself. Specifically, it is well documented that many amputees experience the persistence of severe pain in their missing limb. *See* first sentence at page 57 of N. Postone, 1987, “Phantom Limb Pain. A Review,” *Int’l. Psychiatry in Medicine 17*(1):57-70 (previously submitted as reference C03). In fact, such pain may arise even up to 15 years after amputation (*i.e.*, long after any injury has healed). *Id.* at last full sentence at page 59. The fact that a person can experience severe

pain in a body part no longer present clearly illustrates that pain is distinct from any underlying condition.

Other illustrative examples wherein treatment of an underlying condition will not necessarily treat the associated pain include cancer and inflammatory diseases. In such cases, a tumor or inflammation can trigger a pain mechanism causing the pain to persist even after the tumor or inflammation is no longer present. For example, chronic pain is often seen in post thoracotomy and post mastectomy syndromes, and sympathetically maintained pain has been documented in connection with certain paraneoplastic syndromes (*e.g.*, carcinoma of the prostate, breast, lung, brain and gynecologic tumors). *See* second full paragraph at page 308 and fourth full paragraph at page 313 of Wilsey *et al.*, 2001, “A Review of Sympathetically Maintained Pain Syndromes in the Cancer Pain Population: The spectrum of ambiguous entities of RSD, CRPS, SMP and other pain states related to the sympathetic nervous system”, *Pain Practice* 1(4):307-323 (previously submitted as reference C04).

Applicants respectfully submit that the literature references and examples discussed above demonstrate that pain and any underlying condition are separate entities with respect to their treatment and that pain itself should be considered as a disease in its own right. Thus, Applicants respectfully submit that the pending claims are indeed directed to novel methods of use and do not read upon the subject matter of the '231 patent.

Accordingly, Applicants submit that the rejection of claims 1 and 28-35 under 35 U.S.C. § 102(e) has been overcome and should be withdrawn.

IV. The Rejection Under 35 U.S.C. § 102(e) over U.S. Patent No. 6,897,231 B2 Evidenced by U.S. Patent No. 5,766,605 or U.S. Patent No. 5,434,136

Claims 1 and 28-31 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by the '231 patent evidenced by U.S. Patent No. 5,766,605 A to Sanders *et al.* (the “'605 patent”) or U.S. Patent No. 5,434,136 A to Mathias (the “'136 patent”). In particular, the Examiner has stated that the '231 patent teaches the active agent of the pending claims for the treatment and prevention of lupus erythematosus and asthma, the '605 patent teaches that asthma is autonomic dysfunction, and the '136 patent teaches that lupus erythematosus is autonomic dysfunction.

Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claims 1 and 2 to recite methods of treatment. Claims 28-31 depend directly or indirectly from claim 1.

Applicants submit that the pending method for treatment claims are not anticipated by the '231 patent evidenced by the '605 patent or the '136 patent for the same reasons as set forth above.

Accordingly, Applicants submit that the rejection of claims 1 and 28-31 under 35 U.S.C. § 102(e) has been overcome and should be withdrawn.

V. The Rejection Under 35 U.S.C. § 102(e) over U.S. Patent Application Publication No. 2004/0067953 A1

Claims 1 and 28-31 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2004/0067953 A1 to Stein *et al.* (the "'953 publication"). In particular, the Examiner has stated that the '953 publication teaches the prevention of pain associated with cancer by preventing or treating cancer that causes pain.

Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claims 1 and 2 to recite methods of treatment. Claims 28-31 depend directly or indirectly from claim 1.

Applicants submit that the pending method for treatment claims are not anticipated by the '953 publication for the same reasons as set forth above.

Accordingly, Applicants submit that the rejection of claims 1 and 28-31 under 35 U.S.C. § 102(e) has been overcome and should be withdrawn.

Conclusion

Applicants respectfully request that the above remarks be entered in the present application file. No fee is estimated to be due in connection with this Response other than the fees due in connection with the Petition for Extension of Time and the Request for Continued Examination; however, in the event that any additional fee is due, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Date: March 19, 2008

Respectfully submitted,

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